



Healthy People. Healthy Communities.

Department of Public Health & Human Services

Immunization Program

New VFC Policies for 2013

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Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

**VACCINES FOR CHILDREN
PROGRAM:
VULNERABILITIES IN
VACCINE MANAGEMENT**



Daniel R. Levinson
Inspector General

June 2012
OEI-04-10-00430

Why new requirements in the VFC Program?

Background:

- Office of the Inspector General (OIG) Report – June 2012
 - Improper vaccine storage
 - Expired Vaccine
 - Poor oversight by Immunization Programs

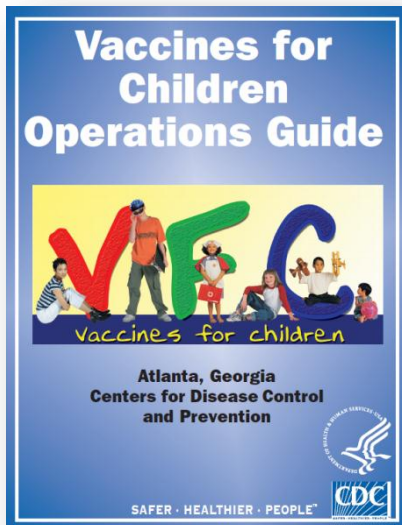
**Vaccine Storage and Handling
INTERIM GUIDANCE**

Introduction

In response to recent scientific studies¹ on equipment used for vaccine storage and a better understanding of best practices for vaccine storage and handling, the Centers for Disease Control and Prevention (CDC) is providing interim guidance on appropriate vaccine storage and handling practices. This guidance is intended for use by all public and private sector providers and, while recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost effective method to phase these recommendations in and more guidance is forthcoming.

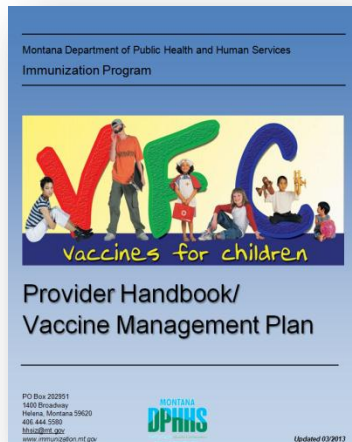
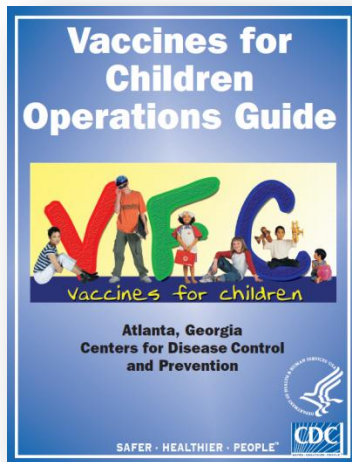
With the goal of improving the way providers store and handle vaccines nationwide, several important changes have been made to previous recommendations issued by CDC, including:

1. Use of a biosafe glycol-encased probe or a similar temperature buffered probe rather than



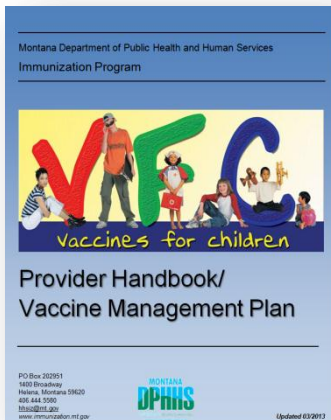
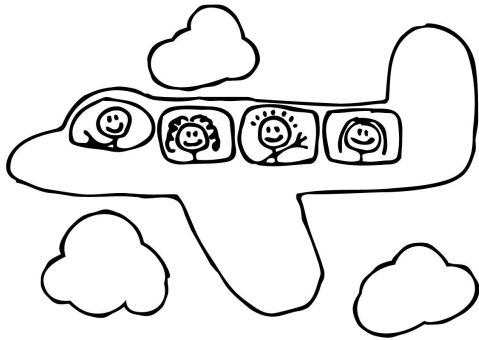
CDC Response:

- October 2012 - Interim Storage and Handling Guidelines (recommendations for all healthcare providers)
- November 2012 - VFC Operations Guide w/ new requirements
- Immunization Programs to implement in 2013



Montana Immunization Program Response:

- Learn, read, and understand the new requirements
- Incorporate into our internal policies and procedures
- Communicate new requirements to providers
- Implement new requirements



Montana Immunization Program

The mission of the Montana Immunization Program is to prevent vaccine preventable disease among all residents throughout their life span by sharing information, managing data, providing education, giving guidance, and overseeing distribution of publicly-funded vaccines.

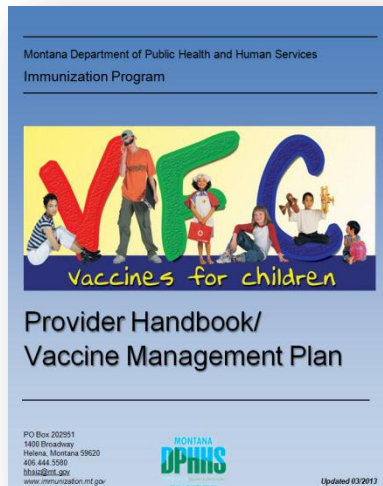
Hot Topic:
New VFC Training and Resource Page

Meaningful Use



Communicating New Requirements:

- **February** - VFC Hot Topics Webinar: New VFC Policies High-level Overview (now)
- **March** - Distribute updated VFC Handbook/Vaccine Management Plan and new data loggers (March)
- **March** - VFC Hot Topics Webinar: New Data Loggers
- **April** - Presentation at Regional Immunization Workshops
- **Monthly** - VFC Hot Topics Webinars



The VFC Handbook/ Vaccine Management Plan :

- **THE** Source for VFC Information!
- Descriptive table of contents
- Appendix with list of 2013 updates by Section, by page number.
- Highlighted text in the document.

APPENDIX-2013 SUMMARY OF HANDBOOK CHANGES		
2013 VFC Provider Handbook Summary of Changes (Highlighted in yellow in body of Handbook)		Page
Section 1-Introduction		
• Added definitions of integrated and aggregate provider in mMTax		7-8
Section 2-Provider Enrollment		
• Added education requirement for re-enrolling and newly enrolling providers		10-11
• Added requirement - providers must notify Immunization Program info changes		10
• Added storage unit approval requirement for newly enrolling providers		11
Section 3-Billing		
• Revised to include new vaccine administration fee cap and guidance from the CDC		13
Section 4-Eligibility		
• Updated to require documenting eligibility screening at every visit		16
• Added website that give locations of FQHCs and RHCs		18
• Updated to distinguish documentation requirements from methods used to determine provider profile		16-17
• Updated state footnotes to include new billing guidance		18-20
Section 5-ACIP		
• Reworded to clarify that VFC providers agree to comply with ACIP schedules, storage, and contraindications		21
Section 6-NCQA		
• Updated to include electronic management of VFCs		23
Section 7-VFC Compliance Site Visits		
• Removed reference to AFIX activities throughout		26-27
• Added Unannounced Storage and Handling Visit requirement		26
Section 8-VFC Requirements Checklist		
• Once (upon enrollment or as needed) -		28
• Added submission of one week of data logger data for storage unit approval		
• Added enrollment education requirement for Vaccine Manager and alternate		29
• Every Vaccination Visit - Revised eligibility screening to include documenting at every visit		29
• Twice Daily - Revised to require the use of State-supplied paper temperature logs		29
• Yearly - Added annual education requirement for Vaccine Manager and alternate		29
• As Needed - Added requirement to have storage units approved by submitting one week of data		29
Section 10-Immunization Resources		
• Updated with current staff contact information		36-38
Section 11-Vaccine Management Plan Introduction		
• Added reference to Section 17 - Vaccine Loss and Replacement Policy		39
• Added heading to emphasize requirement to review Vaccine Management Plan once per calendar year		39
Section 12-Vaccine Management and Emergency Plan		

MT IZ VFC Handbook - Section 8 Appendix-2013 Summary of Handbook Changes (revised 03/01/2013) Page 73 of 77

any required corrective action plans and deadlines for completion.

Site Visit Follow-Up

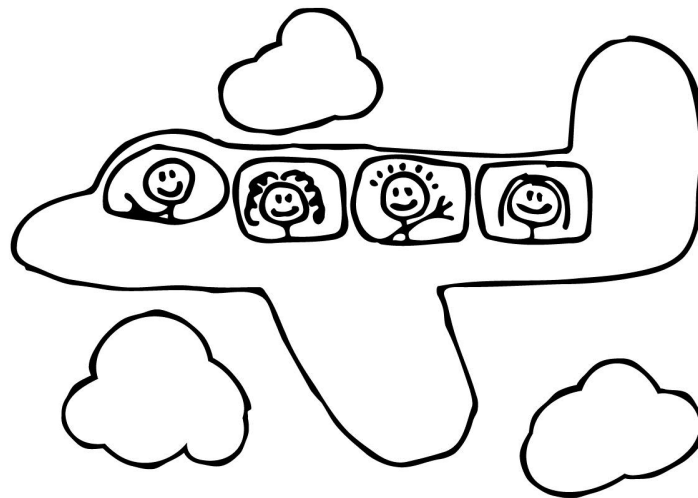
8. Within one month of your visit, you will receive a follow-up letter from the Immunization Program detailing the results of your VFC visit. It will reiterate any VFC compliance issues, corrective action plans, and deadlines from your site visit.
9. In order to remain in good standing with the VFC Program, you must carry out any corrective actions by the deadline. Immunization Program staff will follow up by telephone and email.
10. Immunization Program staff may return to your facility for an educational site visit to address major or complex VFC non-compliance issues.

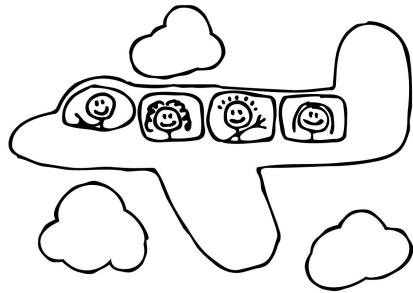
Other Visits from the Montana Immunization Program

- **Unannounced Storage and Handling Visits** - The CDC requires the Immunization Program to perform unannounced "spot check" visits throughout the year. Any active VFC Provider could receive an unannounced visit. The visit will take no longer than 30 minutes and will focus on vaccine storage and handling practices, including an inspection of the VFC vaccine storage units at your facility.

**Will be
mailed to
you in
March!!!**

Overview of New Requirements for 2013:





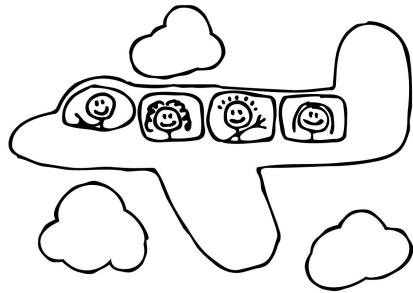
Overview of New Requirements for 2013:

REQUIREMENT

Provider Education:



- Current providers - Annual education requirement for vaccine manager and alternate manager at current VFC provider facilities. Won't be able to re-enroll.
- New providers - Enrollment education requirement for VM and Alternate VM for new providers. Won't be able to complete enrollment.
- **ANYONE** can take the education program. Anytime.



Overview of New Requirements for 2013:

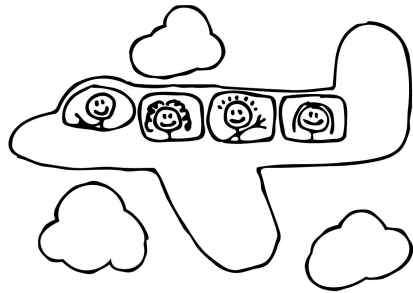
REQUIREMENT

Provider Education:



Details of VFC Provider Education Program at Regional Meetings. Projected launch this summer!!!

- Providers must notify the Immunization Program if Vaccine Manager or Alternate Manager change
- New VM staff must complete the education requirement
- Staff turn-over/ignorance is no excuse for non-compliance.

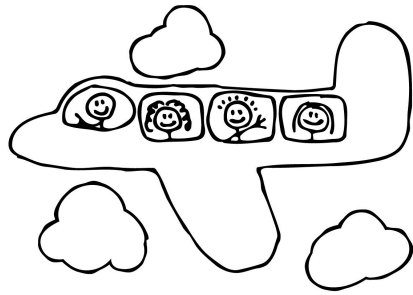


Overview of New Requirements for 2013:

Vaccine Storage and Handling: **REQUIREMENT**



- No dormitory-style storage units. Period.
- Required to certify that you do not use dorm-style units each year during enrollment
- Providers found to be using dorm-style units will be asked to reimburse the cost of the vaccine
- May be inactivated from the program



Overview of New Requirements for 2013:

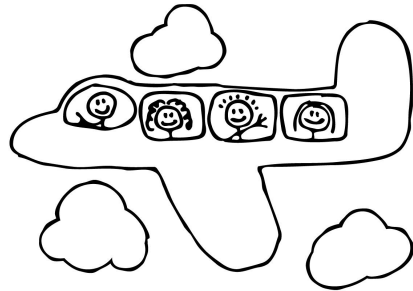
Vaccine Storage and Handling:

REQUIREMENT

- New Data Loggers that comply with CDC interim S & H guidance
- Must return old data loggers to Immunization Program
- Must use new data loggers or have complaint, approved temperature monitoring equipment
- Must record min/max temp
- Will be supplying Data Loggers to birthing hospitals and pharmacies



**Data Logger care packages
(with instructions) will arrive
in March!!!**

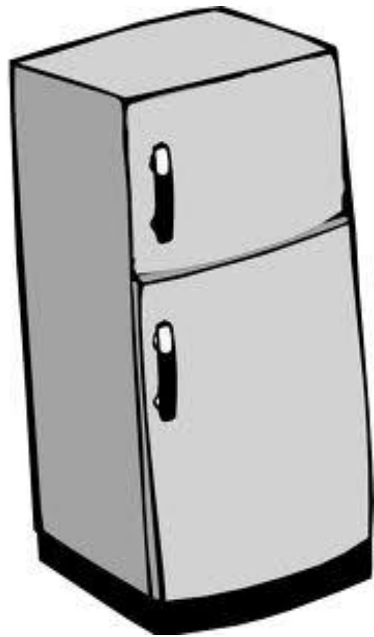


Overview of New Requirements for 2013:

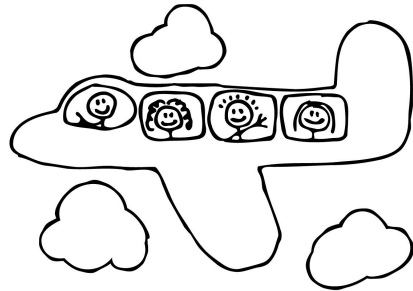
Vaccine Storage and Handling:

REQUIREMENT

- Must have storage units approved before use by submitting one week of temperature data and info on brand/model:
 - Baseline data
 - Quality check on DL installation/storage unit
 - Information on brands/models
- New providers
- providers with new storage units
- Providers re-commissioning units after a repair.



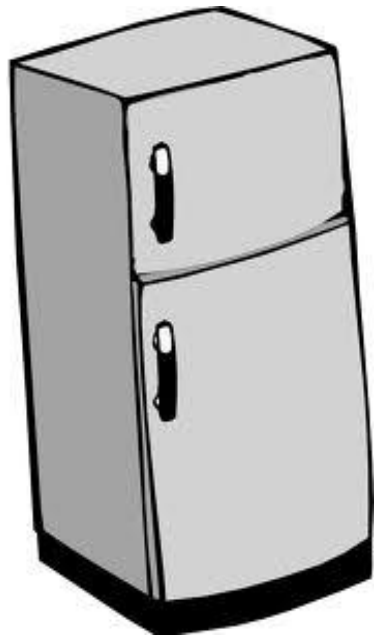
**More info in Data Logger
care packages in
March!!!**



Overview of New Requirements for 2013:

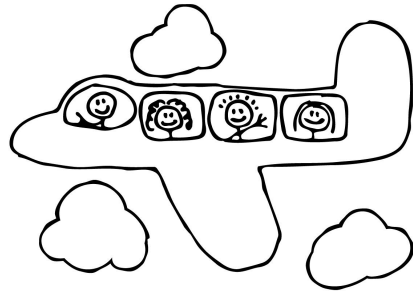
Vaccine Storage and Handling:

Other recommendations in the CDC S & H Interim Guidance



**More info in updated
VFC Handbook!!!**

- CDC recommends stand-alone units over combined units.
- We still allow combined units in VFC Program.
- If acquiring new storage unit – get stand alone!



Overview of New Requirements for 2013:

Wasted and Expired Vaccine:

REQUIREMENTS

- Must develop a process for rotating stock and checking expiration dates WEEKLY
- Record in Section 12



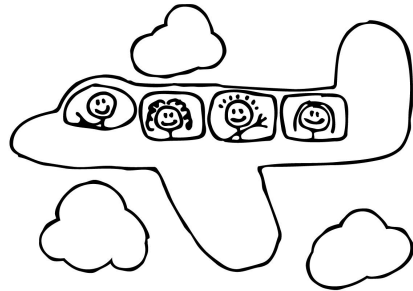
**More info in updated
VFC Handbook!!!**

Vaccine Inventory Management

You must check expiration dates and segregate expired vaccine on a weekly basis. Briefly describe the method you use to ensure that short-dated vaccines are used first:



System for ensuring short-dated vaccines are used first



Overview of New Requirements for 2013:

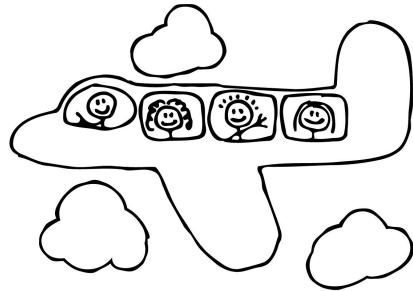
Wasted and Expired Vaccine:

REQUIREMENTS



**More info in updated
VFC Handbook!!!**

- Must return expired/spoiled vaccine to McKesson within 6 months of expiration/spoilage
- Must call McKesson the same day a vaccine shipment arrives or is discovered if you suspect it has been compromised during shipping.
 - Otherwise, they won't take responsibility for replacement.
 - Phone number on packing slip and in Handbook



Overview of New Requirements for 2013:

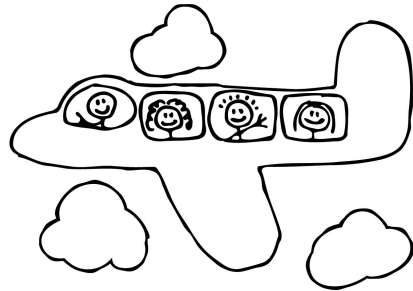
Eligibility Screening:

REQUIREMENTS



**Final policy will be in
updated VFC
Handbook!!!**

- Must screen for AND DOCUMENT eligibility at every immunization visit.
- Old requirement: Must screen at every visit but document only on first visit of the year or if eligibility changes.
- We are seeking clarification from CDC on this.
- Final policy will be in updated Handbook.



Overview of New Requirements for 2013:

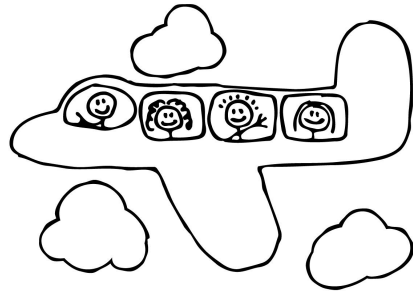
Vaccine Restitution Policy:

REQUIREMENTS

- Providers must reimburse the cost of vaccine lost due to fraud, abuse, or negligence.
 - Dose for dose replacement
 - Direct payment



**Entire policy in
updated VFC
Handbook!!!**



Overview of New Requirements for 2013:

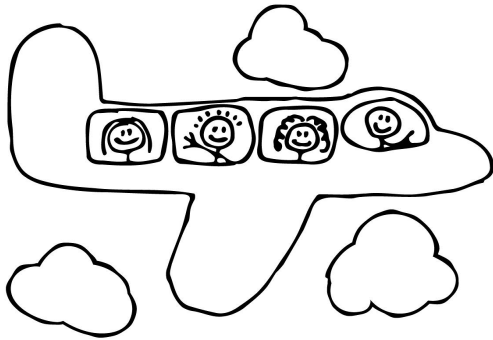
Unannounced Storage and Handling Visits:

REQUIREMENT

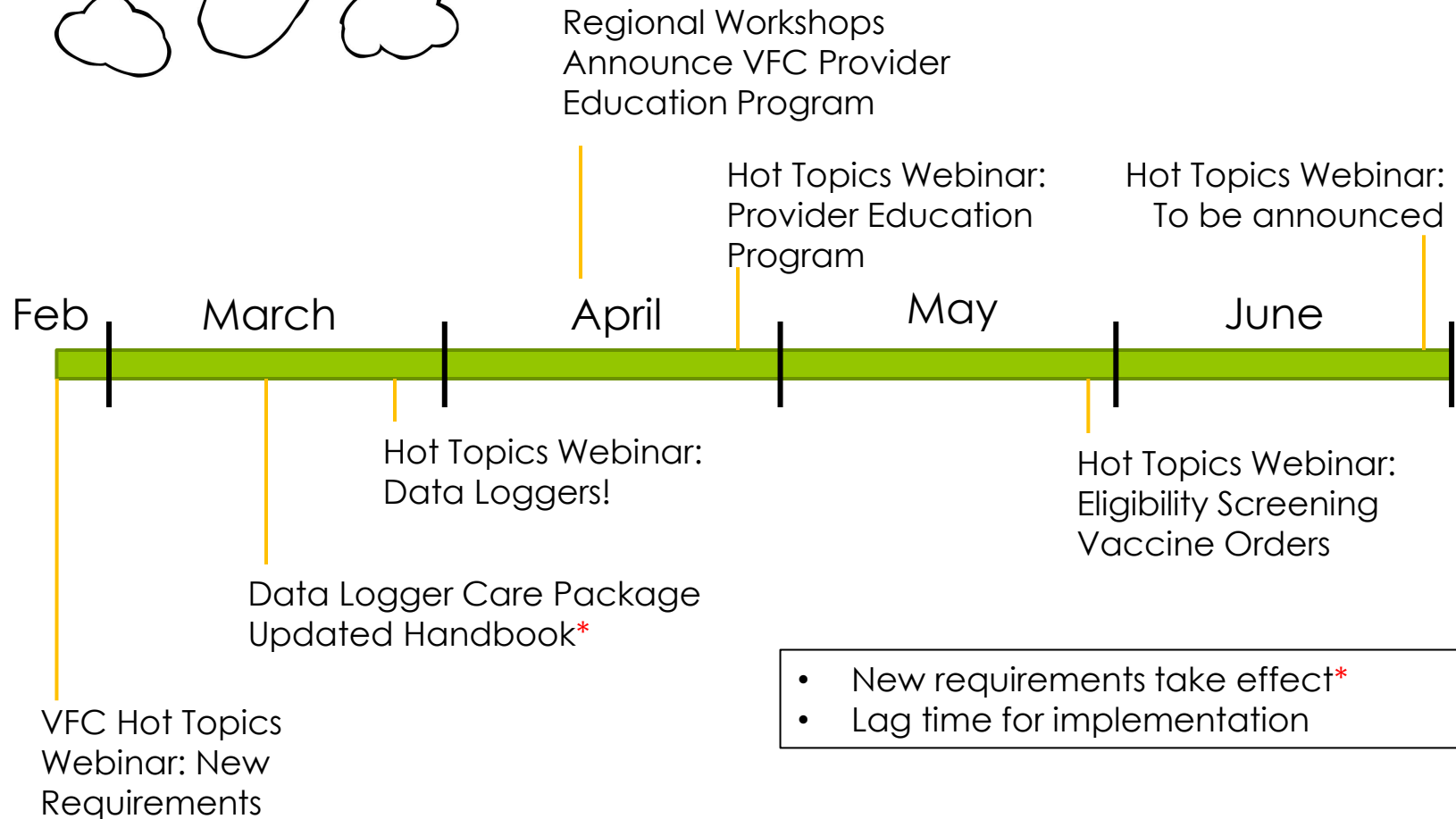
- The Immunization Program must perform unannounced site visits:
 - Focus on storage and handling practices
 - Include inspection of vaccine storage units
 - No longer than 30 minutes

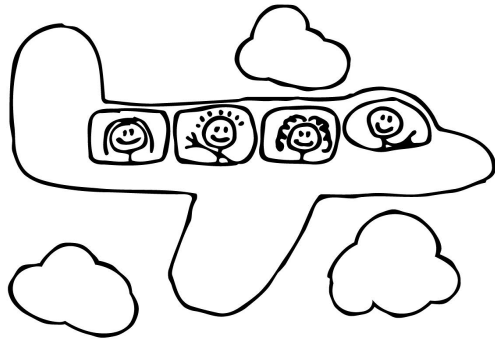


**Entire policy in
updated VFC
Handbook!!!**



New Requirements Timeline:





Resources:

OIG Report:

<https://oig.hhs.gov/oei/reports/oei-04-10-00430.asp>

CDC Interim Vaccine Storage and Handling Guidelines:

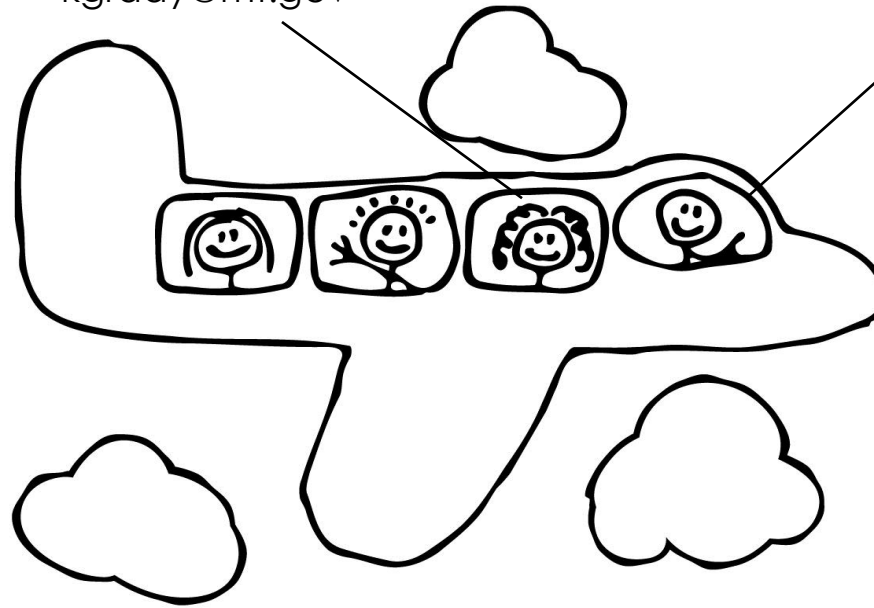
<http://www.cdc.gov/vaccines/recs/storage/interim.htm>

CDC VFC Operations Guide:

<http://www.cdc.gov/vaccines/programs/vfc/awardees/op-guide.html>

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Questions?